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09/593,828

06/13/2000

Steven Rosen

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7507

7590

10/11/2002

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EXAMINER

MONSHIPOURI, MARYAM

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 10/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
**09/593,828**

Applicant(s)  
**Rosen et al.**

Examiner  
**Maryam Monshipouri**

Art Unit  
**1652**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above, claim(s) 1-4 and 13-57 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5-7 and 9-12 is/are allowed.
- 6) ☒ Claim(s) 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of Reference Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 19
- 4) ☐ Interview Summary (PTO-413) Paper No(e). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1652

Claims 5-12 are still at issue and are present for examination. Claims 1-4 and 13-57 are withdrawn as drawn to non-elected inventions and/or species.

Applicants' arguments filed on 7/5/2002, paper No. 17, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

#### ***Claim Objections***

1. Claim 6 is objected to because of the following informalities: SEQ ID NO:11 in the specification is disclosed to encode GST4beta but it is currently recited in claim 6 as encoding GST4alpha. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated DNA sequences encoding SEQ ID NO:8 and homologs thereof (of at least 85% identity to SEQ ID NO:8), does not reasonably provide enablement for isolated DNA sequences that hybridize to DNA sequences encoding said homologs of SEQ ID NO:8 at 50 °C or higher in a solution of 15 mM NaCl and 1.5 mM Na citrate or complementary sequences

Art Unit: 1652

thereof. Claim 8 is directed to isolated DNA sequences that hybridize to those encoding homologs of SEQ ID NO:8 (of at least 85% identity to said sequence) at 50 C in 15 mM NaCl and 1.5 mM sodium citrate wherein said sequences must encode GST.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The specification fails to provide any support about the structural requirements of DNA sequences that can hybridize to those encoding above mentioned homologs of SEQ ID NO:8 with capability of encoding GST. No information about the critical residues which must be present in claimed DNA sequences in order to encode a product with GST4alpha activity can be found in the specification. No examples of such critical residues or sequences encoding such products with GST function are provided either. Current state of prior art indicates that any isolated DNA sequence that can hybridize to those encoding homologs of SEQ ID NO:8 are not necessarily going to encode a product with GST alpha activity. Therefore, the skilled artisan is in need of some guidance about at least the following questions: how many residues encoding the catalytic site are necessary, what should be the nature of such residues and how they should be placed in the claimed DNA sequences such that they encode GST etc., which is currently lacking in the specification.

Art Unit: 1652

Therefore, due to lack of sufficient teachings and examples about the critical residues that must be retained in claimed sequences in order to encode a product with GST function and due to unpredictability of prior art as to how to construct such DNA sequences such that they encode a product with a GST4 alpha function one of skill in art has to go through the burden of undue experimentation in order to make the claimed DNA sequences and as such the claim goes beyond the scope of the disclosure.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claim 8 is rejected under 35 U.S.C. 102(e) as being anticipated by Bistrup et al. (U.S. Patent No. 6,295,192, issued 7/24/2001, cited previously). As indicated previously, Bistrup teaches a DNA sequence encoding GST that has 63.3% local similarity to SEQ ID NO:4 of this invention and can hybridize to DNA sequences encoding 85% homologs of SEQ ID NO:8 under hybridization conditions recited in claim 8, prior to this invention.

Art Unit: 1652

*Allowable Subject Matter*

**Claims 5, 7, and 9-12 are allowed.** This is because DNA sequences encoding SEQ ID NO:8 or claimed homologs thereof with GST4alpha function are free of prior art. Further the prior art does not teach or suggest preparing such specifically claimed DNA sequences. Hence said sequences are also non-obvious. Since said DNA sequences are both novel and non-obvious, hosts comprising said sequences and methods of expressing said sequences are also novel and non-obvious.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Application/Control Number: 09/593,828

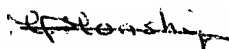
Page 6

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (703) 308-1083. The Examiner can normally be reached daily from 8:30 A.M. to 4:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (703) 308-3804. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

  
Maryam Monshipouri Ph.D.

Primary Examiner